



Atty. Dkt. No. 074129-0510

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Shigeru Kamei et al.

Title: SUSTAINED-RELEASE PREPARATION

Appl. No.: 10/025,967

Filing Date: 12/26/2001

Examiner: D. Lukton

Art Unit: 1653

INFORMATION DISCLOSURE STATEMENT
UNDER 37 CFR §1.56

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Submitted herewith on Form PTO/SB/08 is a listing of documents known to Applicants in order to comply with Applicants' duty of disclosure pursuant to 37 CFR §1.56. A copy of each non-U.S. patent document and each non-patent document is being submitted to comply with the provisions of 37 CFR §1.97 and §1.98.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicants do not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* art reference against the claims of the present application.

TIMING OF THE DISCLOSURE

The listed documents are being submitted in compliance with 37 CFR §1.97(c), before the mailing date of either a final action under 37 CFR §1.113, a notice of allowance under 37 CFR §1.311, or an action that otherwise closes prosecution in the application.

06/20/2005 SDENB081 00000035 10025967

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RELEVANCE OF EACH DOCUMENT

The documents are either in English or are presented with an English abstract or partial translation. English translations of the foreign-language documents are not readily available. However, the absence of such translation does not relieve the PTO from its duty to consider the submitted foreign language documents (37 CFR §1.98 and MPEP §609). English-language abstracts are attached.

Applicants respectfully request that any listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609.

FEE

A fee in connection with submission of an information disclosure statement under 37 CFR §1.97(c) in the amount of \$180.00 in accordance with 37 CFR §1.17(p) is attached.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 CFR §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

Respectfully submitted,

Date June 17, 2005

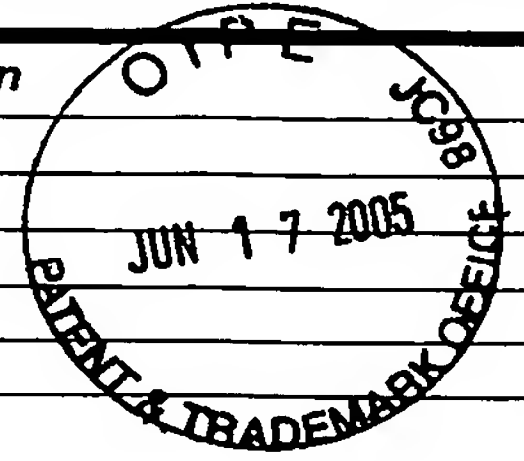
By 

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Matthew E. Mulkeen
Attorney for Applicants
Registration No. 44,250

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Substitute for form 1449B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT Date Submitted: June 17, 2005 (use as many sheets as necessary)				Complete if Known	
				Application Number	10/025,967
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				First Named Inventor	Shigeru Kamei
				Group Art Unit	Unassigned
				Examiner Name	Unassigned
				Attorney Docket Number	074129-0510
Sheet	1	of	5		



U.S. PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code ² (if known)			
	A1	1,995,970		DOROUGH	03/35	
	A2	2,362,511		TEETERS	11/44	
	A3	2,438,208		FLLACHIONE et al.	03/48	
	A4	2,703,316		SCHNEIDER et al.	03/55	
	A5	2,758,987		SAIZBERG	08/56	
	A6	3,043,782		JENSEN	07/62	
	A7	3,092,553		FISHER et al.	06/63	
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	A10	3,539,465		HIESTAND et al.	11/70	
	A11	3,565,869		DePROSPERO	02/71	
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	A13	3,645,911		van BESAUW et al.	02/72	
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	A15	3,755,553		SCRIBNER et al.	08/73	
	A16	3,755,558		SCRIBNER	08/73	
	A17	3,839,297		WASSERMAN et al.	10/75	
	A18	3,882,228		BONCEY	05/75	
	A19	3,890,283		CASEY et al.	06/75	
	A20	3,912,692		CASEY et al.	10/75	
	A21	3,922,338		ESTEVENEL et al.	11/75	
	A22	3,956,172		SAEKI et al.	05/76	
	A23	4,137,921		OKUZUMI et al.	02/79	
	A24	4,234,571		NESTOR et al.	11/80	
	A25	4,249,531		HELLER et al.	02/81	
	A26	4,272,398		JAFFE	06/81	
	A27	4,273,920		NEVIN	06/81	
	A28	4,384,975		FONG	05/83	
	A29	4,389,330		TICE et al.	06/83	
	A30	4,479,911		FONG	10/84	
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	A35	4,652,441		OKADA et al.	03/87	
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	A37	4,710,384		ROTMAN	12/87	
	A38	4,728,721		YAMAMOTO et al.	03/88	
	A39	4,849,228		YAMAMOTO et al.	07/89	

Examiner
Signature

Date
Considered

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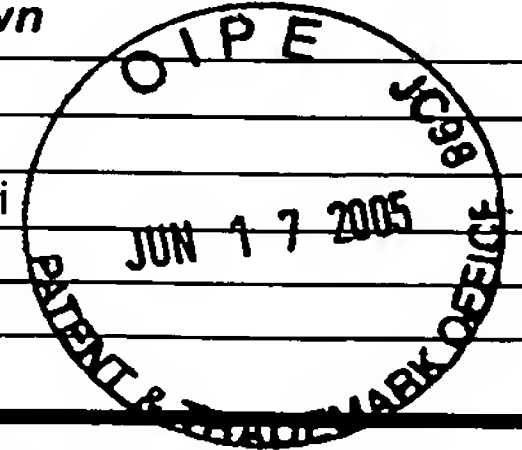
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				First Named Inventor	Shigeru Kamei
				Group Art Unit	Unassigned
				Examiner Name	Unassigned
Sheet	2	of	5	Attorney Docket Number	074129-0510



U.S. PATENT DOCUMENTS

		U.S. Patent Document			
	A40	4,917,893		OKADA et al.	04/90
	A41	4,954,298		YAMAMOTO et al.	09/90
	A42	5,330,767		YAMAMOTO et al.	07/94
	A43	5,480,656		OKADA et al.	01/96
	A44	5,575,987		KAMEI et al.	11/96
	A45	5,631,020		OKADA et al.	05/97
	A46	5,643,607		OKADA et al.	07/97
	A47	5,716,640		KAMEI et al.	02/98
	A48	5,972,891		KAMEI et a.	10/99
	A49	6,528,093		KAMEI et al.	03/2003

FOREIGN PATENT DOCUMENTS

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		Office ³	Number ⁴	Kind Code ⁵ (if known)				
	A50	CA	1 169 090		IMPERIAL CHEMICAL INDUSTRIES PLC	02/1982		
	A51	EP	0 107 591	A2	UNITED STATES SURGICAL CORPORATION	05/1984		
	A52	EP	0 145 240	A2	TAKEDA CHEMICAL INDUSTRIES LTD.	06/1985		
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	A55	FR	2,126,270		DU PONT DE NEMOURS & CO.	02/1972		ABS.
	A56	JP	40-500		FUJI PHOTO FILM CO. LTD.	01/1965	Eng. Translation of Detailed Description, Example 1 and Claim	PART.
	A57	JP	43-3017		DASERU LTD.	02/1968	Eng. Translation of First Three Paragraphs and Claim 1	PART.
	A58	JP	55-114193		HITACHI LTD.	05/1972		ABS.
	A59	UK	1,351,409		SCRIBNER	02/72		
	A60	UK	1,405, 108		DE JAEGER ET AL.	12/71		
	A61	UK	2,145,422 A		SANDOZ LTD.	08/84		
	A62	UK	2,246,514 A		SOCIETE DE CONSILIS DE RECHERCHES ET D' APPLICATIONS SCIENTIFIQUES	05/92		

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Signature

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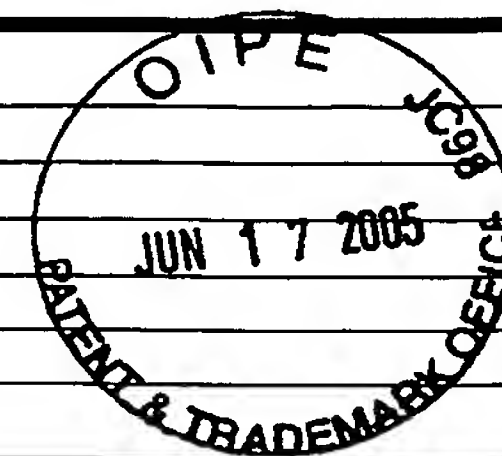
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		Office ³	Number ⁴	Kind Code ⁵ (if known)				
	A63	UK	929,402			11/59		
	A64	WO	89/04673		BOARD OF REGENTS OF THE UNIV. OF TEXAS SYSTEM	06/89		
	A65	WO	98/35654		OAKWOOD LABORATORIES LLC.	09/98		

NON PATENT LITERATURE DOCUMENTS				
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁶	
	A66	ARSHADY,R., "Preparation of biodegradable microspheres and microcapsules: 2. Polyactides and related Polyesters," <u>Journal of Controlled Release</u> , Vol. 17, pp. 1-20, 1991		
	A67	BAKAN, J. A. et al., "Microencapsulation," <u>The Theory and Practice of Industrial Pharmacy</u> , pp. 384-407, 1970		
	A68	CHANG, T., "Biodegradable Semipermeable Microcapsules containing Enzymes, Hormones, Vaccines, and Other Biologicals," <u>Journal of Bioengineering</u> , 1:25-31, 1976		
	A69	DRESSLER, et al., "Viable Prosthetic Interface," <u>J. Biomed. Mater. Res. Sympomium</u> 1:169-178 (1971)		
	A70	<u>Journal of the Chemical Society of Japan</u> , Industrial Chemistry Section, Volume 72, 1969 pp. 493-499 (English Translation of Sections 2.1 and 3.1)		
	A71	<u>Journal of the Chemical Society of Japan</u> , Industrial Chemistry Section, 68(5), English Abstracts, A52-A53, pp. 983-986 (Japanese Text), 1965		
	A72	KEIPERT, S. et al., "Antiglaumakotosahaltige Ophthalmika mit prolongierter Wirkung auf Basis makromolekularer Hilfsstoffe," <u>Die Pharmazie</u> , pp. 594-595 (English Abstract at page 594), August 1990		

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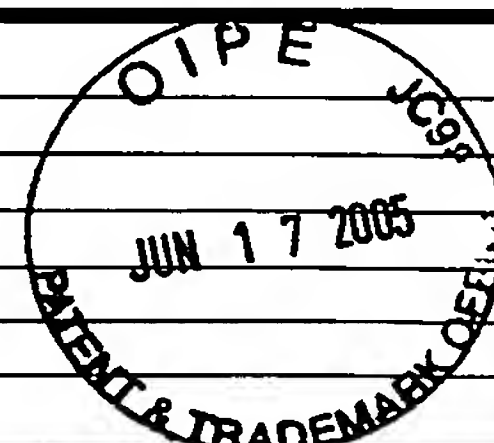
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	A73	KONDO, A., <u>Microcapsule Processing and Technology</u> , Marcel Dekker, Inc., New York, New York (1979), Chapter I, "Microcapsules – General Concepts," pp. 1-10; Chapter III, "Applications and Studies of Microcapsules," pp. 18-26; Chapter IV, "History and Classification of Microencapsulation," pp. 27-34; Chapter X, "Microencapsulation Utilizing In-Liquid Drying Process (Complex Emulsion Method)," pp. 106-120	
	A74	KULKARNI et al, "Biodegradable Poly(lactic acid) Polymers," <u>Journal of Biomedical Materials Research</u> , 5:169-181, 1971	
	A75	KULKARNI et al, "Polyactic Acid for Surgical Implants," <u>Archives of Surgery</u> , 93(5):839-843, November 1966	
	A76	LEWIS, D. et al., "Controlled Release of Bioactive Agents from Lactide/Glycolide Polymers," <u>Biodegradable Polymers as Drug Delivery Systems</u> , pp. 1-41, 1990	
	A77	<u>Microcapsule</u> , Industrial Technology, Library 25, pages 102 (1971)	
	A78	OGAWA, Y. et al, "Controlled Release of LHRH Agonist, Leuprolide Acetate, from Microcapsules: Serum Drug Level Profiles and Pharmacological Effects in Animals," <u>J. Pharma Pharmacol.</u> , PP. 439-444, 1989	
	A79	OGAWA et al., "A new technique to efficiently entrap leuprolide acetate into microcapsules of polylactic acid or copoly (lactic/glycolic) acid." <u>Chem. Pharm. Bull.</u> , Vol. 36, No. 3, pp. 1095-1103, 1988.	
	A80	OKADA, H. et al., "One- and three-month release injectable microspheres of the LH-RH superagonist leuporelin acetate," <u>Advanced Drug Delivery Reviews</u> , 28:43-70, 1997	
	A81	OKADA, H. et al., "One-month release injectable microspheres of leuprolide acetate inhibit steroidogenesis and genital organ growth in rats," <u>International Journal of Pharmaceutics</u> , 54:231-239, 1989	
	A82	OKADA, H. et al., <u>Critical Reviews in Therapeutic Drug Carrier Systems</u> , 12(1):1-99, 1995	
	A83	OMELCZUK, M. et al, "The Influence of Polymer Glass Transition Temperature and Molecular Weight on Drug Release from Tablets Containing Poly(DL-lactic Acid)," <u>Pharmaceutical Research</u> , Vol. 9, No. 1, pp. 26-32, January 1992	
	A84	OMELCZUK, M. et al., "Effect of Thermal Treatment on the Physical-Mechanical and Dissolution Properties of Compacts Containing Biodegradable Polymers," <u>Proceedings of the Ninth International Pharmacuetial Technology Conference Veldhoven, the Netherlands</u> , 1:28-44 (1990)	
	A85	OMELCZUK, M. et al., "The Influence of Thermal Treatment on the Physical-Mechanical and Dissolution Properties of Tablets Containing Poly(DL-Lactic Acid)," <u>Pharmaceutical Research</u> 10(4):542-548 (1993)	

Examiner Signature		Date Considered	
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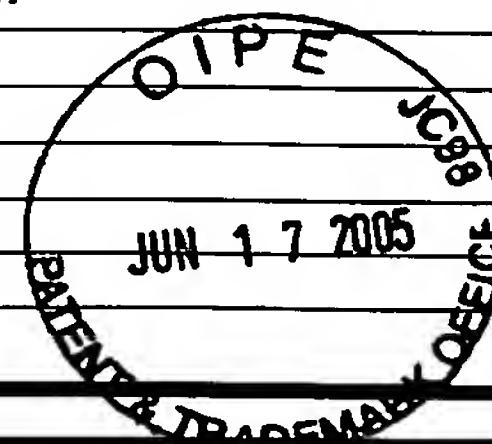
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	A86	PITT, C. et al, "Sustained Drug Delivery Systems, 1. The Permeability of Poly(e-Caprolactone), Poly(DL-Lactic Acid), and Their Copolymers," <u>Journal of Biomedical Materials Research</u> , Vol. 13, pp. 418-507, 1979	
	A87	SANDERS, L. et al, "Controlled Release of a Luteinizing Hormone-Releasing Hormone Analogue from Poly(d, l-lactide-co-glycolide)Microspheres," <u>Journal of Pharmaceutical Sciences</u> , Vol. 73, pp. 1294-1297, September 1994	
	A88	SATO, T. et al, "Porous Biodegradable Microspheres for Controlled Drug Delivery. I. Assessment of Processing Conditions and Solvent Removal Techniques," <u>Pharmaceutical Research</u> , Vol. 5, No. 1, pp. 21-30 January 1988	
	A89	SCHMITT, E. et al., "Importance of Distinct Water Environments in the Hydrolysis of poly(DL-lactide-co-Glycolide)," <u>Macromolecules</u> , 27:743-748, 1994	
	A90	Supplemental Information Disclosure Statement, YAMAMOTO et al, Serial No. 858,040 filed 11/3/87 with the U.S. Patent and Trademark Office	
	A91	<u>The Pharmacopoeia of Japan</u> , Tenth Edition, pp. 16- 21, 1981	
	A92	WANG, H.T. et al., "Influence of formulation methods on the in vitro controlled release of protein from poly (ester) microspheres," <u>Journal of Controlled Release</u> 17:23-31, 1991	
	A93	WOO, B. H. et al, "Preparation, characterization and in vivo evaluation of 120-day poly(D,L-lactide) Leuprolide microspheres," <u>Journal of Controlled Release</u> , 75:307-315, 2001	

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